

original U.S. national phase filing.

The information relating to the deposit of the microorganism that is the subject of this application has also been added to the specification. The applicant has also provided us with a photocopy of the official receipt issued by the Japanese agency and a copy is attached as Exhibit A to this Amendment.

The Claim Amendments

Claims 1-7 and 9-11 remain in the case; claim 8 has been cancelled. Claim 1 has been amended to better conform to customary U.S. claim practice and to remove the term "general" in characterizing formula (I). Similar amendments have also been made to claims 2-6.

Independent process claim 7 has been amended in form and also to limit the process to the specified microbial strain.

Claims 9 and 11 have been amended to delete the term "general" as requested by the Examiner and to substitute the use of the singular form of "caprazamycin" in the interest of clarity and for grammatical reasons. Claim 11 is also amended to delete the reference to the deposit facility in Japan, the details of which are now recited in the specification.

Should the Examiner find that any further amendments as to form are required for clarity, we respectfully request that the Examiner initiate a telephone interview with the undersigned for the purpose of expediting the entry of any such amendments.

The Amended Claims Define Patentable Subject Matter

The office action asserts that claims 9 and 10 are "substantial duplicates". We note that claim 10 is dependent from claim 9 and has been amended. Claim 9 identifies the invention simply as a "pharmaceutical composition", while dependent claim 10 identifies that the pharmaceutical effect is "antibacterial". Claim 10 is directed to a species of pharmaceutical composition. We respectfully submit that applicant is entitled to claim the invention in its own terms, so long as the claims are accurate and are not prolix.

Reconsideration and withdrawal of any implied objection to claim 10 is respectfully requested.

With respect to the "product of nature" ground of rejection of claim 11 under §102(b), reconsideration is respectfully requested. The claimed biologically pure culture of the MK730-62F2 strain of this claim is not simply "a product of nature". Although the microorganism exists in nature, and was in fact collected from one of the Hawaiian Islands, applicant thereafter isolated the pure material from which are derived the claimed compounds exhibiting antibacterial properties. It is well established in this art that the first to take the steps to isolate and recover useful compounds is entitled to protection under U.S. patent law, even though the underlying source is a product of nature. As amended, claim 11 is patentable.

Original claim 11 was also rejected on the prior art under §102(b) or, alternatively, under §103(a) as obvious over USP 4,699,879 or the Kimura publication. Applicant wishes to note that the '879 patent, at column 8 (Example 1) discloses a

microbial species *Streptomyces hachijoensis*. The cited Kimura et al. reference has also been reviewed and, for convenience a copy is attached to this Amendment as Exhibit B. Kimura discloses a liposidomycin-producing strain, *Streptomyces griseosporeus* and also makes reference to an earlier publication *J. Antibiotics.*, 38, 1617(1985), a copy of which is also attached as Exhibit C. The latter publication reveals that the liposidomycin-producing microorganism is *Streptomyces griseosporeus*.

Applicant is also attached as Exhibit E a copy of the *International Journal of Systemic Bacteriology*, Vol. 18, No. 2 pages 128-129 that is referred to in column 6 lines 13-19 of the cited '879 patent wherein the microbiological properties of *Streptomyces hachijoensis* (FERM P-7218) are described.

Also enclosed are copies of pages 303, 305 and 306 of the *International Journal of Systemic Bacteriology*, Vol. 22 (1972), wherein the microbiological properties of *Streptomyces griseosporeus* are described.

With respect to *Streptomyces hachijoensis*, its mature spore chains are short, generally 3 to 10 spores per chain and the color of its culture colony shows aerial mass color of red color series as described in the above literature.

The applicant's claimed MK730-62F2 strain has aerial phyphae of graying white to light gray color with formation of spirals (see page 24, line 9 of the specification and Table 8 at page 29-32 of the specification).

As for *Streptomyces griseosporeus*, this microorganism commonly has flexuous spore chains and its aerial mass color is of the gray color series as described in the above

literature.

The morphological properties of the claimed MK730-62F2 stain vary greatly in important respects from those of the known *Streptomyces hachijoensis* and the known *Streptomyces griseosporeus* so that these three microorganisms cannot be found to be identical to each other.

In view of the clear differences it will be apparent to one of ordinary skill in art that the subject matter of amended claim 11 is neither anticipated nor obvious. Withdrawal of the rejection is therefore respectfully requested.

Conclusion

The amendments to the specification and claims are, we believe, fully responsive to the issues raised by the office action. The differences between the claimed subject matter are apparent and any *prima facie* case of obviousness has been overcome by the additional evidence submitted and the arguments presented above.



Favorable reconsideration and allowance of the amended claims is respectfully requested.

Respectfully submitted

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A handwritten signature in cursive ink that appears to read "Thomas E. Spath".

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